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an amount of soluble RAGE (sRAGE) effective to inhibit binding of the  $\beta$ -sheet fibril to RAGE.

a2  
cont

58. (new) A method of inhibiting of the binding of a  $\beta$ -sheet fibril to RAGE on the surface of a cell of a subject, wherein the cell is located outside the central nervous system of the subject, which comprises administering to the subject an amount of a peptide fragment of sRAGE identical to the V-domain of sRAGE effective to inhibit binding of the  $\beta$ -sheet fibril to RAGE.

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**REMARKS**

Claims 1-40 are pending. Applicants have canceled claims 1-40 without prejudice to applicants' right to pursue the subject matter of these claims in a future application claiming priority under 35 U.S.C. §120. Claims 41-58 have been introduced. Support for these claims may be found in the specification, *inter alia*, on page 18, line 15 to page 20, line 30; page 21, line 32 to page 26, line 5; and page 27, line 26 to page 32, line 34. Applicants maintain that these amendments raise no issue of new matter.

**Restriction/Election**

The Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. §121:

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- I. Claims 1-26, drawn to a method of inhibiting binding of proteins on the surface of cells, classified in class 435, subclass 7.1.
- II. Claims 27-33, drawn to a method of treatment, classified in class 424, subclass 184.1.
- III. Claims 34, 36-38, drawn to a method of determining whether a compound inhibits of  $\beta$ -sheet fibril to RAGE, classified in class 435, subclass 7.1.
- IV. Claims 35 and 39, drawn to a compound that inhibits binding of  $\beta$ -sheet fibril to RAGE, class and subclass determined by structure.
- V. Claim 40, drawn to a method of preparing a composition, classified in class 514, subclass 2.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions I, II, III and V are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process

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steps, and goals.

The Examiner stated that invention IV is unrelated to Inventions I, II, and V. The Examiner stated that inventions are unrelated if it can be shown that they are not capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner stated that in the instant case the different inventions are not disclosed as capable of use together.

The Examiner stated that inventions III and IV are related as product and processes of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). The Examiner stated that in the instant case the peptide or compound of Invention IV can be used to make an antibody.

#### Applicants' Reply

In reply, applicants elect Group II, claims 27-33 drawn to methods of treatment. Applicants have canceled claims 1-40 and have introduced new claims 41-58 which are directed to methods of treatment of a subject. Applicants submit that new claims 41-58

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are drawn to the invention of Group II and request that the Examiner enter the Amendment and examine claims 41-58.

Species Election

The Examiner stated that this application contains claims directed to the following patentably distinct species of the claimed Inventive Group I. The Examiner stated that Applicant must select a species from Groups A), B) and C):

A) A  $\beta$ -sheet fibril:

- a) amyloid fibril.
- b) amyloid- $\beta$  peptide.
- c) amylin.
- d) amyloid A.
- e) prion-derived peptide.
- f) transthyretin.
- g) cystatin C.
- h) gelsolin.
- i) a peptide capable of forming amyloid.

B) A compound capable of inhibiting binding of  $\beta$ -sheet fibril:

- a) sRAGE.
- b) an anti-RAGE antibody; a human, humanized, or chimeric anti-RAGE antibody.

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- c) a peptide
- d) a peptidomimetic
- e) a nucleic acid, or
- f) an organic compound with a molecular weight less than 500 daltons.

C) A Cell Type:

- a) a neuronal cell.
- b) an endothelial cell.
- c) a glial cell.
- d) a microglial cell.
- e) a smooth muscle cell.
- f) a somatic cell
- g) a bone marrow cell.
- h) a liver cell.
- i) an intestinal cell.
- j) a germ cell.
- k) a myocyte.
- l) a mononuclear phagocyte
- m) an endothelial cell
- n) a tumor cell
- o) a stem cell
- p) a RAGE-transfected cell

The Examiner stated that applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits

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to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner stated that currently, Claim 1 is found to be generic.

The Examiner stated that Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The Examiner stated that an argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The Examiner stated that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. The Examiner stated that if claims are added after the election, applicant must indicate which are readable upon the elected species.

#### Applicants' Reply

In reply, applicants elect from Group A: (i) a peptide capable of forming amyloid; from Group B: (a) sRAGE; and from Group C: (1) a mononuclear phagocyte.



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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

No, other than the \$55.00 one month extension of time fee, is deemed necessary in connection with the filing of this Amendment. If any additional fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents,  
Washington, D.C. 20231.

5/11/99  
Date

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